



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/712,266

11/14/2003

Richard Bruce Brandon

40383-0006

7950

26633 7590 04/17/2009
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92122

EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

04/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,266	Applicant(s) BRANDON ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-146 is/are pending in the application.
- 4a) Of the above claim(s) 96-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-95 is/are rejected.
- 7) ☒ Claim(s) 71-72, 79, 80, 84-88, and 90-95 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03152004</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Applicant's election with traverse of Group II (claims 71-95, 99-119, and 131-146) and specie H (fifth broad form of present invention in paragraphs 00025-00050 corresponding to claims 71-95), filed 2/4/09, is acknowledged. Claims 96-98 and 120-130 are withdrawn from consideration as being drawn to a non-elected Group. Claims 99-119 and 131-146 are withdrawn from consideration as being drawn to non-elected species.

Applicant's traversal is on the grounds that at least all claims in the invention of Group II could be examined without a burden to the Examiner.

The Applicant's request to withdraw the species election was found unpersuasive because of the following reasons (summarized from the restriction paper):

The species are independent or distinct because claims to the different species recite mutually exclusive characteristics such as species. In addition, these species are not obvious variants of each other based on the current record.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The requirements are still deemed proper and are therefore made FINAL.

Drawings, filed 11/14/03, are accepted by the Examiner.

Art Unit: 1631

The information disclosure statement, filed 3/15/04, has been considered by the Examiner.

Claims herein under examination are 71-95.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as in paragraphs 000416, 000436, and 000469. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 71-72, 79, 80, 84-88, and 90-95 objected to because of the following minor informalities:

Claims 71-72, 79, 80, 84-88, and 90-95 contain capitalized words throughout their sentences. Only the first word in each sentence should be capitalized.

Claim 79 recites "71a" which is not a claim number.

Claim 93 recites "each diagnostic signatures" which is awkward.

Appropriate correction is requested.

Art Unit: 1631

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 71-95 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 71-95 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. It is noted that the instant claim 71 recites “comparing the subject data”; however, this step is not a transformation of an article to a different state or thing. It is further noted that claims 71-95 do not explicitly require that the steps of the claimed method are performed on a machine. Applicant is cautioned against introduction of new matter in an amendment.

Art Unit: 1631

Claims 71-95 are drawn to a process. For a process that comprises an abstract idea to be statutory, it must comprise a practical application of the abstract idea. Claimed subject matter may require a practical application by claiming, or requiring use of, a machine, or by requiring a physical transformation of an article to a different state or thing (In Re Bilski (88 USPQ2d 1385 Fed. Cir. 2008)). Even if claimed subject matter claims, or requires use of, a machine, the claimed subject matter may not require a practical application. One indication that claimed subject matter requires a practical application is an explicit requirement of a useful concrete, and tangible result as discussed in In re Alappat (31 USPQ2d 1545 Fed. Cir. 1994):

Although many, or arguably even all, ²² of the means elements recited in claim 15 represent circuitry elements that perform mathematical calculations, which is essentially true of all digital electrical circuits, the claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means. ²³ This is not a disembodied mathematical concept which may be characterized as an “abstract idea,” but rather a specific machine to produce a useful, concrete, and tangible result.

The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a practical application (i.e. useful, concrete, and tangible result). In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be “useful” the claim must produce a result that is specific and substantial. For a claim to be “concrete” the process must have a result that is reproducible. For a claim to be “tangible” the process must

Art Unit: 1631

produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 71-95 do not require production of a tangible result in a form that is understandable to the user of the process or apparatus. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, to a user, in a graphical format, or in a user readable format, or by including a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 71 recites the limitations "the level", "the results", and "the presence" in lines 4, 11, and 12. There is insufficient antecedent basis for these limitations in the claim as there is no previous mention of these limitations. Clarification of this issue via clearer claim wording is requested. Claims 72-95 are also rejected due to their dependency from claim 71.

Art Unit: 1631

Claim 72 recites the limitations "the stage" and "the degree" in lines 3-5. There is insufficient antecedent basis for these limitations in the claim as there is no previous mention of these limitations. Clarification of this issue via clearer claim wording is requested.

Claims 73-75, 79-80, 83-86, and 94 recite "being" sufficiently statistically significant, greater, less, or "being performed" which lack clarity. Since the verbs are recited in the passive tense, it is unclear whether these limitations are intended to be actual method steps, are intended results, or some other scenario. Applicant is reminded that any method steps must be clearly recited in active, positive language. Clarification of this issue is requested. Claims 87-93 are also rejected due to their dependency from claim 86.

Claim 79 recites "the parameters being representative of the level or abundance of a molecule selected from one or more of" while claim 71 (from which claim 79 depends) recites "parameters being representative of the level, abundance or functional activity of a gene expression product in the cells" which lacks clarity. It is noted that not all of the parameter choices in claim 79 fall under the category of the description of parameters recited in claim 71. It is unclear if Applicant intends the parameters in claim 79 to replace the parameters of claim 71 or some other scenario. Clarification of this issue via clearer claim wording is requested.

Claim 80 recites the limitations "the immune system" in the last line. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of this limitation. Clarification of this issue via clearer claim wording is requested.

Claim 81 recites the limitations "the individuals" in line 2. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of this limitation.

Art Unit: 1631

Clarification of this issue via clearer claim wording is requested. Claim 82 is also rejected due to their dependency from claim 81.

Claim 85 recites steps including a, b, and c which lack clarity. It is unclear if Applicant intends these steps to replace steps a, b, and c in claim 71 from which it depends. Clarification of this issue via clearer claim wording is requested.

Claim 85 recites the limitation "the results" in line 12. There is insufficient antecedent basis for this limitation in the claim. There are previous comparisons in claims 71 and 85, making it unclear to which results are being referred. Clarification of this issue via clearer claim wording is requested.

Claim 86 recites the limitation "the individual" in line 5. There is insufficient antecedent basis for this limitation in the claim. While there is previous mention of plural individuals, it is unclear to which particular individual is being referred. Clarification of this issue via clearer claim wording is requested. Claims 87-93 are also rejected due to their dependency from claim 86.

Claim 89 recites "representing" which lack clarity. Since the verb is recited in the passive tense, it is unclear whether this limitation is intended to be an actual method step, is an intended result, or some other scenario. Applicant is reminded that any method steps must be clearly recited in active, positive language. Clarification of this issue is requested.

Claim 95 recites the limitation "the subjects and individuals" in line 1. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of plural subjects and individuals. Clarification of this issue via clearer claim wording is requested.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 11/14/02. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b). The effective filing date for this instant application is 7/9/03.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 71-95 are rejected under 35 U.S.C. 102(e) as being anticipated by Hamilton et al. (US 2003/0229451 A1).

Hamilton et al. disclose a method of determining the status of a subject (abstract, 0013, 0018) including obtaining subject data from cells from a single test including values of a plurality of parameters representative of gene expression product levels and indicative of the subject's status (0013-0017, 0054-0071), comparing the subject data to predetermined data (i.e. reference data) and determining the status of the subject indicating the presence, absence or degree of one or more conditions (0017, 0072-0075, 0080-0081, 0133), as stated in instant claim

Art Unit: 1631

71, as well as medical practitioner confirmation (0061-0062), as stated instant claim 85.

Hamilton et al. disclose the indication of a stage of a condition (0080, 0087), as stated in instant claim 72. Hamilton et al. disclose parameter numbers being sufficiently statistically significant to allow a number of conditions to be distinguished (0043, 0086), as stated in instant claim 73.

Hamilton et al. disclose parameters being greater than 100, 1000, or less than 6000 parameters (0068, 0135, 0148, 0259), as stated in instant claims 74-76. Hamilton et al. disclose generating a report representing the status of the subject (0013, 0017, 0022, 0090, 0100, 0114, 0190), as stated in instant claim 77. Hamilton et al. disclose validating drug compounds and producing a compilation of health or wellness profiles including assessing health outcomes such as general health, physical function, role of function due to physical limitations, vitality and energy (abstract, 0009, 0054-0055, 0062, 0075) which represents determining the ability to perform in a sporting event in accordance with the presence or absence of a condition, as stated in instant claim 78. Hamilton et al. disclose levels of genes and proteins (0055), as stated in instant claim 79. Hamilton et al. disclose reference data including phenotypic data of individuals and subject data including phenotypic data (0052, 0053, 0057, 0060, 0017), as stated in instant claim 81.

Hamilton et al. disclose comparing subject data to predetermined (i.e. reference) data having one or more phenotypic traits in common with the subject (0013, 0043, 0080), as stated in instant claim 82. Hamilton et al. disclose predetermined data being diagnostic signatures, including determining a diagnostic signature for a respective condition by data mining subject data related to individuals with known conditions or degrees of conditions including a range of values for some parameters (0013, 0017, 0071, 0080-0082, 0085-0087, 0091, 0133), as stated in instant claim 83. Hamilton et al. disclose data determined by clinical trials and diagnosis of conditions

Art Unit: 1631

within subjects (0061, 0385, 0054, 0062, 0071, 0080), as stated in instant claim 84. Hamilton et al. disclose determining a diagnostic signature by obtaining data relating to individuals including indication status, respective values for parameters, selecting one or more groups, and determining a range of parameters values for each group in accordance to values and range representing a diagnostic signature (0013, 0017, 0071, 0080-0082, 0085-0087, 0091, 0120 (i.e. different distributional parameters), 0133, 0030, 0039, 0136-0139, 0143-0144, 0148-0149, i.e. clustering inherently selectively excludes, 0129, 0134, 0208, 0397), as stated in instant claim 86, as well as the comparing and excluding steps in instant claim 87, medical practitioner confirmation (0061-0062), comparing (0017), and updating (0088), as stated in instant claim 88, as well as comparing and excluding steps in instant claim 90. Hamilton et al. disclose predetermined criteria using quality control criteria (0120), as stated in instant claim 89. Hamilton et al. disclose determining parameters that allow a group to be distinguished from each other group as well as determining parameters that allow the degree of a condition to be determined and determining a range of parameter values (0013, 0017, 0043, 0060-00610071, 0080-0082, 0085-0087, 0091, 0133, 0030, 0039, 0136-0139, 0143-0144, 0148-0149), as stated in instant claims 91 and 92. Hamilton et al. disclose obtaining data for an individual, comparing parameter values for the individual to the respective diagnostic signature and revising the diagnostic signature in accordance with an unsuccessful comparison (0086-0088 (i.e. refining diagnostic signature), 0013, 0017, 0053, 0080-0083), as stated in instant claim 93. Hamilton et al. disclose using a system including an end station coupled to a base station via communications network to receive data, determine status, and transfer indication of status to the end station via the network (0018, 0022, 0098-0099, 0100, 0102-0120), as stated in instant claim 94. Hamilton

Art Unit: 1631

et al. disclose subjects and individuals such as humans, equines, canines (0057), as stated in instant claim 95.

Thus, Hamilton et al. anticipate the instant invention.

Other prior art

Although not being used as prior art, US 2004/0009479 is being made of record. In US 2004/0009479, Wohlgemuth et al. discuss diagnosing and monitoring auto immune diseases via gene expression level detection.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

Art Unit: 1631

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

April 14, 2009

/Carolyn Smith/
Primary Examiner
AU 1631